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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/402,273 12/13/99 ULRICH

J 9950-0002

HM12/0327

EXAMINER

DIANNE E REED  
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PORTOLA VALLEY CA 94028

DIBRINO, M

ART UNIT	PAPER NUMBER
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1644

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DATE MAILED: 03/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No. 09/402,273	Applicant Ulrich et al.
Examiner Marianne DiBrino	Group Art Unit 1644



Responsive to communication(s) filed on \_\_\_\_\_

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claim

Claim(s) 1-5 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) \_\_\_\_\_ is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims 1-5 are subject to restriction or election requirement.

### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

*No Shown* *Electronically transmitted* *Review*

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

#### DETAILED ACTION

1. **Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

I. Claims 1 and 2, drawn to a pharmaceutical composition comprising tyrosine, an optionally modified allergen and 3-DMPL.

II. Claims 3 and 4, drawn to a method of treating a patient with allergy or preventing allergy comprising administration of the pharmaceutical composition of claim 1.

III. Claim 5, drawn to a process for the preparation of the pharmaceutical composition of claim 1.

3. The inventions listed as Groups I, II and III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Claim 1 of the instant application does not provide a technical feature that is distinguished over the prior art, as evidenced by WO 96/34626 (IDS reference "AF") in view of WO 92/16556 (IDS REFERENCE "AE").

WO 96/34626 teaches a pharmaceutical composition comprising tyrosine and an optionally modified allergen, i.e., a polymerized allergen (especially claims). WO 96/34626 does not teach the said composition comprises 3-DMPL. WO 92/16556 teaches a pharmaceutical composition comprising a modified or unmodified peptide antigen from HIV gp160 and 3-DMPL, and further teaches that 3-DMPL is an adjuvant and adjuvants are useful to present immunogens effectively to the host immune system (especially claims, Abstract, page 8 at lines

20-34 and page 10 at lines 27-30). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have included the 3-DMPL adjuvant of WO 92/16556 in the pharmaceutical composition taught by WO 96/34626 because WO 92/16556 teaches that adjuvants are useful to present immunogens effectively to the host immune system.

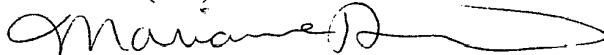
Therefore, since the technical feature recited in claim 1 lacks an inventive step, the instant invention lacks Unity of Invention.

4. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne DiBrino whose telephone number is (703) 308-0061. The examiner can normally be reached Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.



Marianne DiBrino, Ph.D.  
Patent Examiner  
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Technology Center 1600  
March 9, 2001



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SUPERVISORY PATENT EXAMINER  
GROUP 1640 1680